II. Rejection under 35 U.S.C. § 103

The Examiner has maintained the rejection of claims 23-62 under 35 U.S.C. § 103(a) as being unpatentable over WO 97/24107 to Dias in view of WO 97/19998 to Aaslyng for the reasons set forth in the Office Action dated February 14, 2003 and as set forth on page 2 of the present Final Office Action.

The Examiner states that Dias "discloses the use of the enzymes in the dyeing composition and [particularly] peroxidase enzymes, which are, used [specifically] as a hydrogen peroxide generating enzyme." Final Office Action at 2. The Examiner then states that Aaslyng "teaches that enzymes are used in the dyeing composition [to] provide improved dyeing composition over the composition that comprises traditional hydrogen peroxide...." Id. The Examiner concludes therefore, that "a person of the ordinary skill in the art would be motivated to incorporate the laccase enzyme as taught by Aaslyng in the dyeing composition of Dias with a reasonable expectation of success...." Id.

Applicants respectfully disagree with the Examiner's reasoning and his ultimate conclusion. The Examiner has used the key phrases "motivated" and "reasonable expectation of success" but has not supported their use. The threshold for establishing motivation or suggestion to modify a prior art reference is high. The Examiner can satisfy the burden of establishing a *prima facie* case of obviousness "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to modify the relevant teachings of the references." *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 Fed. Cir. 1988) (citations omitted) (emphasis added).

The Examiner has not specifically shown, as he is required by law to do, how one skilled in the art would have been motivated to use the laccase from Aaslyng as an alternative source for hydrogen peroxide, to be utilized in Dias. Dias discloses the use of enzymes, but not of the laccase type that Aaslyng claims. As argued before on the record, Dias discloses enzymes as merely optional, but not as the sole oxidizing agent. Instead, the focus in Dias is on water-soluble peroxygen oxidizing agents, with enzymes being only an afterthought. That alone would be enough to prevent one of ordinary skill in the art from using an enzyme outside of the disclosed list. See Dias p. 38.

Further, and importantly, Dias uses the enzyme peroxidase as a source for hydrogen peroxide. Aaslyng teaches that laccase enzymes may have certain advantages over hydrogen peroxide in hair dyes, and the Examiner thus attempts to transplant the laccase enzymes into Dias, presumably switching the peroxidase for laccase. However, such a substitution is simply not feasible.

Specifically, Aaslyng teaches that to overcome the disadvantage created by the use of hydrogen peroxide, a laccase enzyme may be used "to replace" hydrogen peroxide as an oxidizing agent in an oxidative dye composition. Aaslyng, page 2, lines 25-26. As explained in Aaslyng at pages 5-6, laccases are multi-copper containing enzymes that catalyze the oxidation of phenols. In other words, the enzyme oxidizes the dye precursor directly, *without any production of hydrogen peroxide.* This is in contrast to 2-electron enzymes, such as the peroxidases and other enzymes taught by Dias at pages 38-39, which oxidize their substrate by producing hydrogen peroxide, which then oxidizes the dye precursor. Thus there is no reason why one of ordinary skill in the art would take the hydrogen-peroxide free enzymatic oxidizing system of

Aaslyng and put it into Dias, which teaches different types of enzymes, i.e., those that produce hydrogen peroxide. The Examiner's assumption that all enzymatic oxidizing agents are interchangeable is incorrect.

Without a suggestion for modification in the references themselves, the Examiner cannot properly make this rejection. Here, the Examiner has not pointed to any actual, objective evidence of record that would have led one of ordinary skill in the art to put the laccases of Aaslyng into the dye compositions of Dias and to expect the feasibility or utility of such a modification. Broad conclusory statements regarding the teachings of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). As such, the Examiner has not cited any "clear and particular" evidence that would provide the necessary evidence of a suggestion, teaching, or motivation to modify Dias with Aaslyng.

In addition, as argued on the record, Aaslyng does not teach or suggest the use of its laccase with any alkalinizing agent. But Dias teaches the use of several buffering agents, which include alkalinizing agents. See Dias pp. 32-34. Thus, even if one attempted to use a laccase in place of the enzymes listed by Dias, the references do not suggest any reasonable expectation of success. Applicants have previously relied on Zviak's THE SCIENCE OF HAIR CARE to argue that varying any element in a hair dye can cause a major change, especially in the field of oxidative coupling reactions.

In the Appeal Brief filed on December 11, 2002, which addressed an obviousness rejection under Audousset (U.S. 5,769,903) in view of Aaslyng, Applicants illustrated that other scientists also agreed with Zviak. Applicants set forth evidence that unpredictability derives from at least the environment in which dyeing occurs, and the

complexity of the chemical reactions, as is the case with the present invention.

According to Pohl:

> Since a number of competing chemical reactions are going on simultaneously to effect the final color result, it may be imagined that making natural-appearing shades of oxidation dyes products is very complicated. The actual chemistry is even further complicated: the hair plays a part in the final result, in that the diffusion of the intermediates into the air, both before and after any chemical reactions have occurred, plays an important part of the process, and one cannot predict the final color result from a knowledge of the solution chemistry of the dyes.

S. Pohl, Ph.D., "The Chemistry of Hair Dyes," Cosmetics & Toiletries, vol. 103, May 1988, pp. 57-66 at page 64.

Applicants also noted that other scientists comment that the unpredictability in the hair dyeing art is even greater based on the variability of each person's hair taken together with the inability to predict how the particular complex chemical reactions are affected by an individual's hair. In general,

> [a] further complication in predicting the outcome of competing reactions inside the hair fiber is that it will depend not only on the relative reactivity of the competing couplers, but also on their relative rates of diffusion from the dye bath into the hair. Furthermore, for competing reactions taking place inside a swollen keratin fiber, we do not know to what extent the rate of the coupling reactions will be diffusion controlled.

J. Corbett, *Chemistry of Hair Colorant Processes - Science as an aid to Formulation and Development,*" J. Soc. Cosmet. Chem., 35, Sept./Oct. 1984, pp. 297-310 at 299.

Applicants refer to these arguments of records because they are very relevant to the present rejection over Dias in view of Aaslyng. In view of the scientific opinion set forth above, the Examiner has failed to provide any evidence to show why one of ordinary skill in the art would have reasonably expected a successful dye to be formed from the proposed modification.

To make a prima facie case of obviousness, the Examiner must specifically point to evidence that suggests that there would have been a reasonable expectation of success if the references were combined as he proposes. The combination would involve picking a single ingredient out of a successful laccase-oxidized composition (Aaslyng) and putting it into a successful peroxide-oxidized dye composition (Dias) with no guidance whatsoever to do so other than the fact that both compositions relate to oxidation hair dyeing. This hardly constitutes the basis for a "reasonable expectation," particularly given the requirements of the case law and the state of the art discussed above.

Hence, neither reference can suggest the success of the proposed combination, and one of ordinary skill in the art would not have had the reasonable expectation of success for making the modification proposed by the Examiner. One of ordinary skill in the art, knowing that the art is unpredictable, would not have reasonably expected success based on the disclosures of record.

Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103.